



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

IAM2 training documentation

IAM2 changes training documentation



User management

Slide 3

- Request a unique EMA account
- Manage my unique EMA account
- Request a new password

Access management

Slide 9

- Request role and permissions
- Approve role and permissions
- Manage role and permissions
- Access EV applications

Organisation management

Slide 21

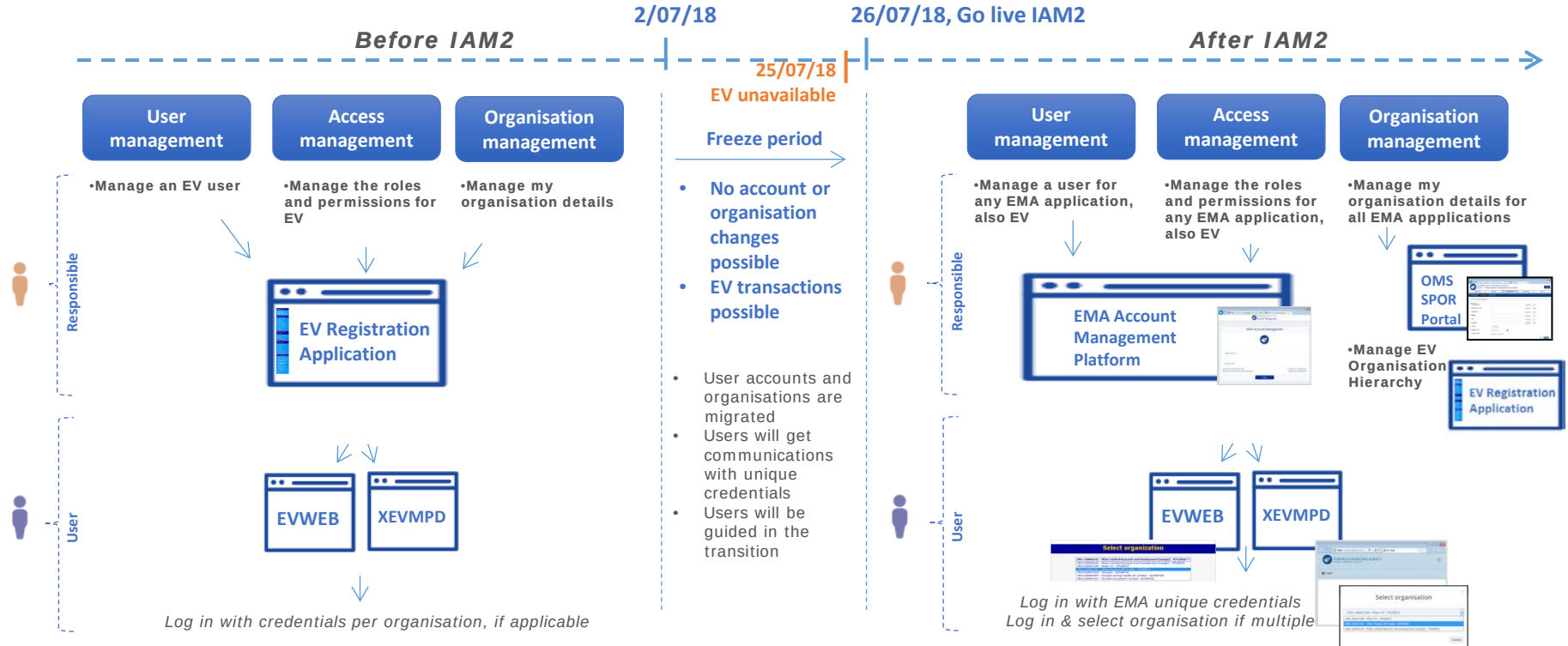
- Create a new organisation or update an existing one
- Manage the organisation hierarchy in EV

IAM2 project

The change introduced



EUROPEAN MEDICINES AGENCY



User
management

Access
management

Organisation
management

- **Request a unique EMA account**

Users may create an EMA account if they do not have one yet.

- **Manage my unique EMA account**

Users may update their email address and mobile number or change their password.

- **Request a new password**

Users may request a new password if they forgot.

IAM2 project

User management



EUROPEAN MEDICINES AGENCY



All Users

User
management

Access
management

Organisation
management



→ Request a unique EMA account
→ <https://register.ema.europa.eu/identityiq/login.jsf>

Note: this is only applicable to new users. Existing EV users will receive a unique EMA account

EMA Account Management

Username

Password

Create a new EMA account
Not sure if you have an EMA account?

Forgot your password?
Forgot your username?

Login

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Username

Password

Create a new EMA account
Not sure if you have an EMA account?

Login

EMA - Full registration form

Submit the following form to register:

First Name *

Last Name *

Email *

Phone *

Country *

Gender *

DOB *

Health (optional)

This is an optional field, but we will use this information for security purposes in order to register to your account. Please include the international dialing code in front of your mobile number.

Data Protection Statement

Consent

Go to EMA Account
registration platform

Select to create an EMA account

Fill out the form and submit

IAM2 project

User management



User
management



→ Request a
→ <https://register>

EMA Account Management



Username

Password

Create a new EMA account
Not sure if you have an EMA account?

Forgot your password?
Forgot your username?

Login

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Go to EMA Account
registration platform

Select

EMA - Self-service Registration Form

Submit the following form to register.

First Name *

This is used to create your username and to address you in email correspondence.

Last Name *

This is used to create your username and to address you in email correspondence.

Email *

We require a valid/active email address to create an EMA Account.

Password *

Please enter a password that you want to use to access your EMA Account. The password must have at least 8 characters and must contain upper case, lower case, numeric and special characters.

Confirm Password *

Mobile (optional)

This is an optional field. We will only use this information for security messages or alerts in relation to your account. Please include the international dialling code in front of your mobile number.

Data Protection Statement

Policy

DATA PROTECTION STATEMENT

Your personal data are processed in accordance with Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. To find out more about your rights and about how the EMA processes personal data, please check the Privacy Statement on EMA's website.

The information we collect is used to manage direct access to EMA's systems and to verify users' accounts. We will collect and use personal data such as your e-mail address and phone number (if provided), to communicate any next steps or key changes to the system. Your data will be deleted after 180 days of inactivity on our systems.

IAM2 project

User management



EUROPEAN MEDICINES AGENCY



All Users

User
management

Access
management

Organisation
management



→ **Manage my unique EMA account / update e-mail or mobile**

→ <https://register.ema.europa.eu/identityiq/login.jsf>

EMA Account Management

Username

Password

Create a new EMA account?
Not sure if you have an EMA account?

Forgot your password?
Forgot your username?

Login

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EUROPEAN MEDICINES AGENCY
Account Management

Home My Work

Home

View Identity >

Manage My Access >

Track My Requests >

Manage Passwords >

Manage Accounts >

Notifications 0

Forms 0

Approvals 0

Your Pending Approvals

Latest Forms

Currently no data

Currently no data

Edit Identity

EMA - Edit Identity Form

Update Attributes

Internal users cannot change any of these values. External users may update their email address and mobile number.

Username
berghmans_a

First Name
Arnaut

Last Name
Berghmans

Email
arnaut.berghmans@gmail.com

Mobile
+32xxxxxxxxx

Cancel Submit

*Log into EMA Account
registration platform*

Select 'View Identity'

*Users may update their
email address and mobile
number and submit*



User
management

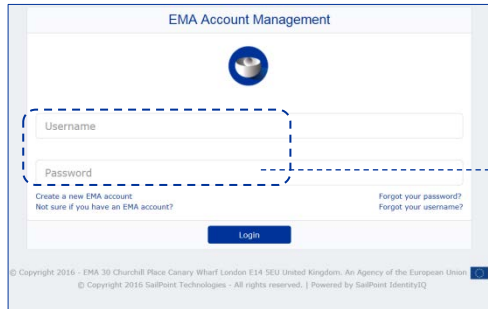
Access
management

Organisation
management



→ **Manage my unique EMA account / change password**

→ <https://register.ema.europa.eu/identityiq/login.jsf>



EMA Account Management

Username

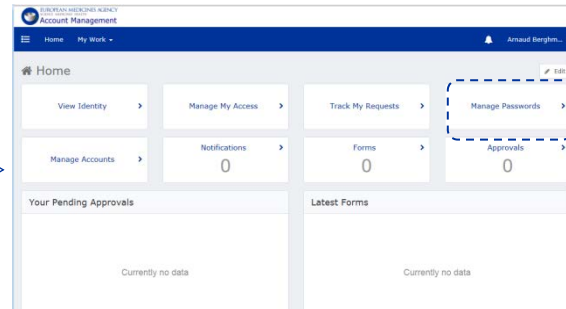
Password

Create a new EMA account?
Not sure if you have an EMA account?

Forgot your password?
Forgot your username?

Login

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Account Management

Home My Work

View Identity > Manage My Access > Track My Requests > Manage Passwords >

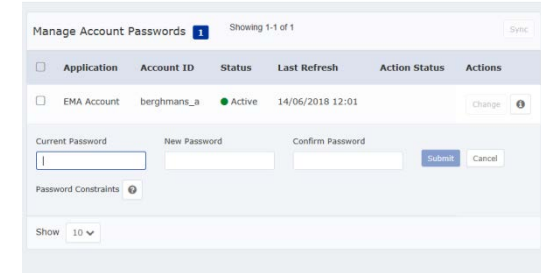
Manage Accounts > Notifications > Forms > Approvals >

Your Pending Approvals

Latest Forms

Currently no data

Currently no data



Manage Account Passwords 1 Showing 1-1 of 1 Sync

Application	Account ID	Status	Last Refresh	Action Status	Actions
☐	EMA Account	berghmans_a	Active	14/06/2018 12:01	Change ⓘ

Current Password New Password Confirm Password

Submit Cancel

Password Constraints ⓘ

Show 10 ▾

*Log into EMA Account
registration platform*

Select 'Manage Passwords'

*Select 'Change' and
confirm current and new
password before
submitting*



All Users

User
management

Access
management

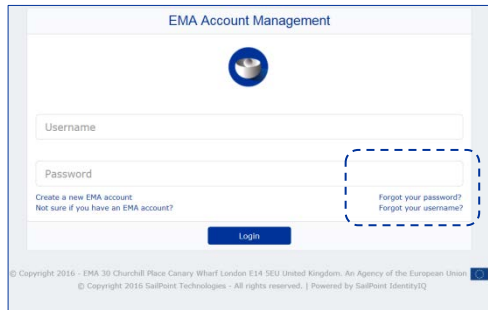
Organisation
management



Request a new password



<https://register.ema.europa.eu/identityiq/login.jsf>



EMA Account Management

Username

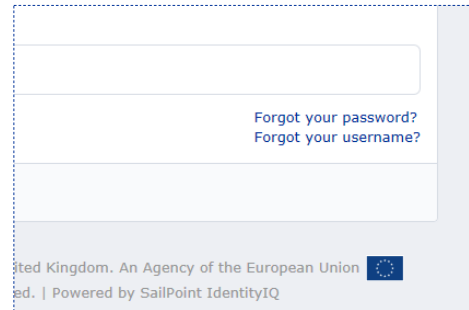
Password

Create a new EMA account
Not sure if you have an EMA account?

Forgot your password?
Forgot your username?

Login

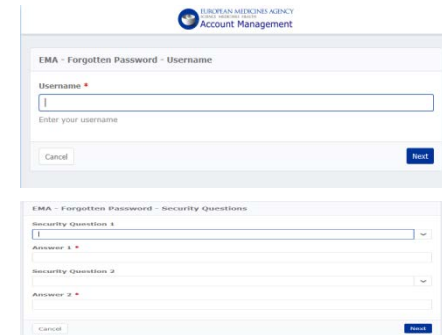
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Forgot your password?
Forgot your username?

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EMA - Forgotten Password - Username

Username *

Enter your username

Cancel Next

EMA - Forgotten Password - Security Questions

Security Question 1

Answer 1 *

Security Question 2

Answer 2 *

Cancel Next

*Go to EMA Account
registration platform*

Select forgot your password

*Fill out the forms and submit.
The user will get an e-mail within
minutes to reset the password*

User
management

Access
management

Organisation
management

- **Request role and permissions**

Users may request a role for any EMA application, also for EV.

- **Approve role and permissions**

Users may grant a role for any EMA application to a user.

- **Manage role and permissions**

Users may control the access (revoke, change) roles for user belonging to an organisation.

- **Access EV applications**

Users can enter into EV applications, when granted roles that provide permission to do so.



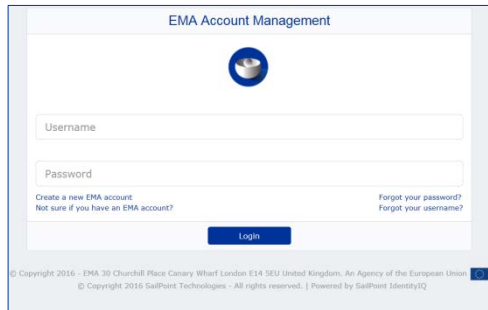
User
management

Access
management

Organisation
management



- Request role and permissions for any EMA application, also EV (1 / 2)
- <https://register.ema.europa.eu/identityiq/login.jsf>



EMA Account Management



Username

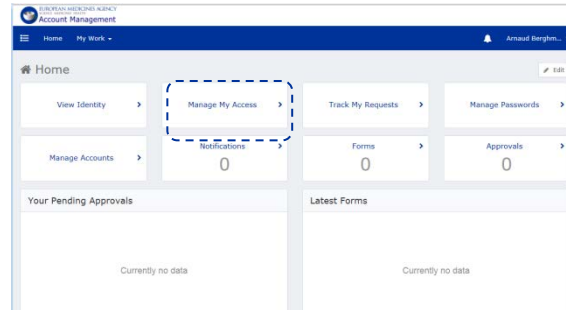
Password

Create a new EMA account
Not sure if you have an EMA account?

Forgot your password?
Forgot your username?

Login

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Log in with EMA unique
credentials

Select 'Manage My Access'



All Users

User
management

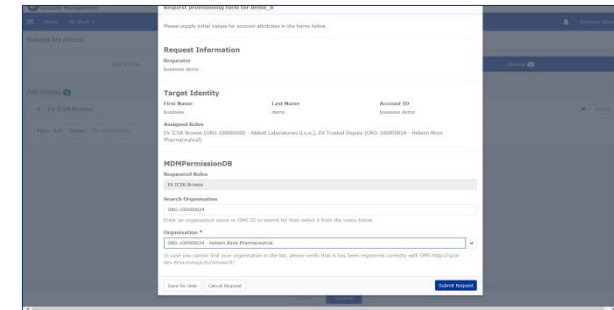
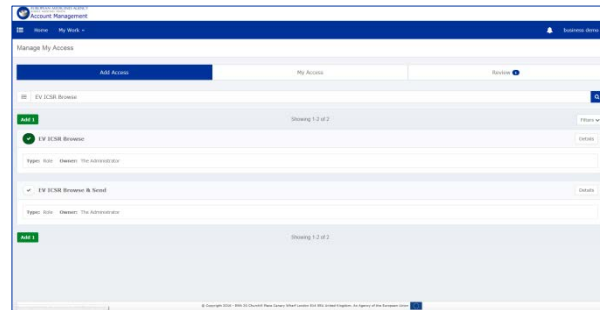
Access
management

Organisation
management



→ Request role and permissions for any EMA application, also EV (2 / 2)

→ <https://register.ema.europa.eu/identityiq/login.jsf>



Request a role for a given application

*Select for which given organisation
that role need to be exercised and
submit*

IAM2 project

Access management / Overview of EV related roles



EUROPEAN MEDICINES AGENCY

Role name	MAH Description	NCA Description	CS/NCS Description
EV NCA Responsible		This user is the RP of the NCA or PH centre. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).	This role is not applicable for NCS/CS
EU QPPV	This user is the EU QPPV of the Organisation selected. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).	This role is not applicable for NCA	This role is not applicable for NCS/CS
EV CS/NCS Responsible	This role is not applicable for MAH	This role is not applicable for NCA	This user is the RP of the Organisation selected. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).
EV NCA Trusted Deputy	This role is not applicable for MAH	This user is the administrator role for an Organisation. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).	This role is not applicable for NCS/CS
EV Trusted Deputy	This user is the administrator role for an Organisation. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).	This role is not applicable for NCA	This user is the administrator role for an Organisation. They can perform administrative actions (such as approving user access), and also administrative tasks such as: build hierarchies; create additional transmission virtual affiliates; manage users assignment to the virtual affiliates).
xEVMPPD QPPV	Only for MAH, the user will select this role if they have been appointed by their EU QPPV or responsible as QPPV of an authorised medicinal product	This role is not applicable for NCA	This role is not applicable for NCS/CS
EV ICSR Browse	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. He can access ICSR messages of the organisation assigned to.	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. He can access ICSR messages of the organisation assigned to.	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. He can access ICSR messages of the organisation assigned to.
EV ICSR Browse & Send	This allows the individual user to access EudraVigilance to perform queries as well as to create and send ICSRs. In addition, the user can receive safety messages with one or several ICSRs, store the safety messages locally and generate acknowledgement messages.	This allows the individual user to access EudraVigilance to perform queries as well as to create and send ICSRs. In addition, the user can receive safety messages with one or several ICSRs, store the safety messages locally and generate acknowledgement messages.	This allows the individual user to access EudraVigilance to perform queries as well as to create and send ICSRs. In addition, the user can receive safety messages with one or several ICSRs, store the safety messages locally and generate acknowledgement messages.
EV L2B Access	Access right that allows the user to visualize personal data of the patient. (Narrative) Level 2B access is an additional and specific access right that can be assigned by the QPPV or trusted deputy to registered EVWEB or EVDAS users of the MAH. It should only be assigned to users related to MAH and users assigned to an organisation with an existing role. (Only cumulative role). Previously, the users will only have L3.	This role is not applicable for NCA	This role is not applicable for NCS/CS
EV MPR Browse	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. They can access MPR of the organisation assigned to.	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. They can access MPR of the organisation assigned to.	This allows the individual user to access EudraVigilance and to perform queries on a read only basis. They can access MPR of the organisation assigned to.
EV MPR Browse & Send	This allows the individual user to access EudraVigilance to perform queries regarding Medical Products Reports(MPR), as well as to create and send extended medicinal product reports by means of extended medicinal product report messages and generate acknowledgement messages.	This role is not applicable for NCA	This allows the individual user to access EudraVigilance to perform queries regarding Medical Products Reports(MPR), as well as to create and send extended medicinal product reports by means of extended medicinal product report messages and generate acknowledgement messages.
EVDAS NCA Scientific	This role is not applicable for MAH	Role for EVDAS with access to individual case report forms and CIOMS	This role is not applicable for NCS/CS
EVDAS MAH Scientific	Role for EVDAS with access to individual case report forms and CIOMS	This role is not applicable for NCA	This role is not applicable for NCS/CS
EV Contributor	This role allows the user to be assigned to a Virtual affiliate by a responsible role of the organisation.		

Manage My Access

Add Access

My Access

Review 1

EV ICSR Browse



Add 1

Showing 1-2 of 2

Filters



EV ICSR Browse

Details

Type: Role Owner: The Administrator

1/select the role
by clicking on the
flag, so it turns
green

2/after selection of
the roles click on
review and submit



EV ICSR Browse & Send

Details

Type: Role Owner: The Administrator

Add 1

Showing 1-2 of 2

IAM2 project

Access management



EUROPEAN MEDICINES AGENCY

Account Management

Home My Work

Manage My Access

Add Access

Add Access 1

EV ICSR Browse

Type: Role Owner: The Administrator

Request provisioning form for demo_b

Please supply initial values for account attributes in the forms below.

Request Information

Requester

business demo

Target Identity

First Name

business

Last Name

demo

Account ID

business demo

Assigned Roles

EV ICSR Browse (ORG-100000005 - Abbott Laboratories d.o.o.), EV Trusted Deputy (ORG-100000024 - Helsinn Birex Pharmaceutical)

MDMPermissionDB

Requested Roles

EV ICSR Browse

Search Organisation

ORG-100000024

Enter an organisation name or OMS ID to search for then select it from the menu below.

Organisation *

ORG-100000024 - Helsinn Birex Pharmaceutical

In case you cannot find your organisation in the list, please verify that it has been registered correctly with OMS <http://spor-dev.ema.europa.eu/omswi/#/>

Save for later

Cancel Request

Submit Request



business demo

Review 1



Details

Responsible

Access management

Organisation management



The screenshot displays the Oracle Cloud Management console interface. At the top, there's a navigation bar with 'Home' and 'My Work' links. Below this, a horizontal menu contains several options: 'View Identity', 'Manage My Account', 'Track My Requests', 'Manage Passwords', 'Manage Accounts', and 'Notifications'. The 'Forms' icon, which is a yellow document with a pencil, is highlighted with a red dashed box in the left navigation pane. The main content area is divided into two sections: 'Your Pending Approvals' and 'Latest Forms'. The 'Your Pending Approvals' section shows a table with columns for 'Approval For', 'Requester', and 'Date'. The 'Latest Forms' section shows a placeholder for 'Currently no data'.

Approval For	Requester	Date
User Demos	User Demos	25/05/2018 10:01

Currently no data

The screenshot shows the 'Approval' page in the 'Security Management' console. The page has a blue header with the 'Security Management' logo and navigation links. The main content area is white and contains the following information:

- Identity:** User Device - 1 Request
- Requested by User Device:** Assigned for TV-1538 Review (ORG: 1000000000) Approval # [link] Track Request [link]
- Requested for User Device:** Assigned for TV-1538 Review (ORG: 1000000000) Review (Info: Pharmacovigilance)
- Approved by:** [Empty field]
- Buttons:** Approve, Deny, Cancel

A red dashed box highlights the 'Approved by' field, which is currently empty. Below the field are three buttons: 'Approve', 'Deny', and 'Cancel'.

View the open role requests by selecting 'Approvals'

Approve a role request for a given application and a given organisation

IAM2 project

The change introduced



EUROPEAN MEDICINES AGENCY



Home My Work

Charles Smith

Home

Edit

View Identity

Manage My Access

Track My Requests

Manage Passwords

Manage Accounts

Notifications

1

Forms

0

Approvals

1

EV Role Admin

Your Pending Approvals

Approval For	Requester	Date
User Demos	User Demos	25/05/2018 10:03

All

Latest Forms

Currently no data

All



IAM2 project

The change introduced



Home My Work

Charles Smith

< Approval

Identity: User Demos | **1 Request**

Requested on: 25 May 2018 10:03:22

Actions

Approval Details

Requested by: User Demos **Assigned to:** EV ICSR Browse (ORG-100000024) Approvers

Track Request

Add: EV ICSR Browse (ORG-100000024 - Helsinn Birex Pharmaceutical)

Details

Action: Add

Approve

Deny

Undo

1/approve or deny
the role by clicking
on the designated
action buttons





User
management

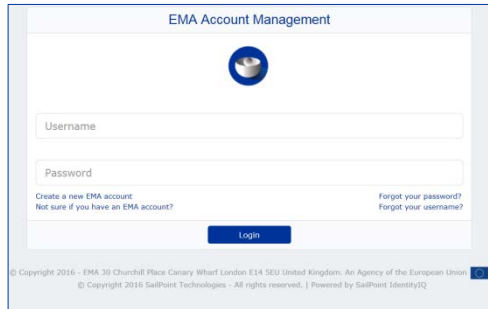
Access
management

Organisation
management



→ **Manage role and permissions of users belonging to the QPPV -Responsible's organisation**

→ <https://register.ema.europa.eu/identityiq/login.jsf>



EMA Account Management

Username

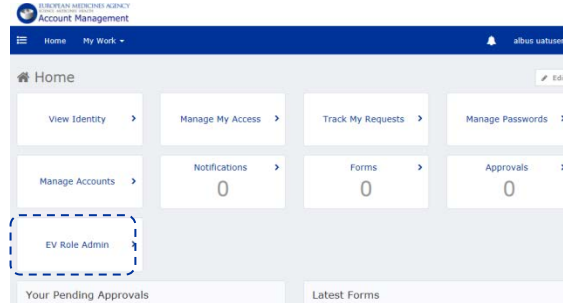
Password

Create a new EMA account
Not sure if you have an EMA account?

Forgot your password?
Forgot your username?

Login

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Home My Work

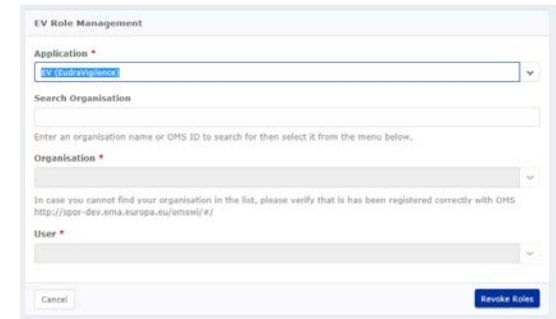
Home

View Identity > Manage My Access > Track My Requests > Manage Passwords >

Manage Accounts > Notifications > Forms > Approvals >

EV Role Admin

Your Pending Approvals Latest Forms



EV Role Management

Application *

EV (EudraVigilance)

Search Organisation

Enter an organisation name or QMS ID to search for then select it from the menu below.

Organisation *

In case you cannot find your organisation in the list, please verify that it has been registered correctly with QMS
<http://spor-dev.ema.europa.eu/omsel/e/>

User *

Cancel Revoke Roles

*Log in with EMA unique
credentials*

Select 'EV Role Admin'

*Select , the application, a given
organisation and a given user
whose role(s) you want to revoke*

IAM2 project

The change introduced



EUROPEAN MEDICINES AGENCY



All Users

User
management

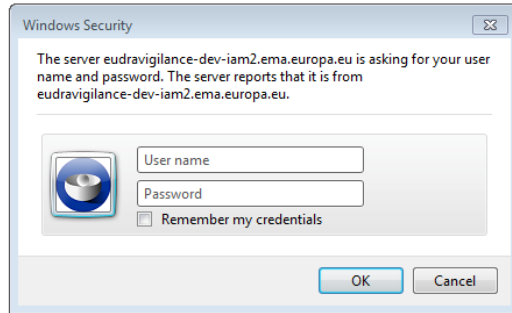
Access
management

Organisation
management



→ Access EV applications

→ EVWEB



*Log in with EMA unique
credentials*

*select the organisation on behalf
which actions need to be performed*

*Good
to go*

IAM2 project

The change introduced



EUROPEAN MEDICINES AGENCY



All Users

User
management

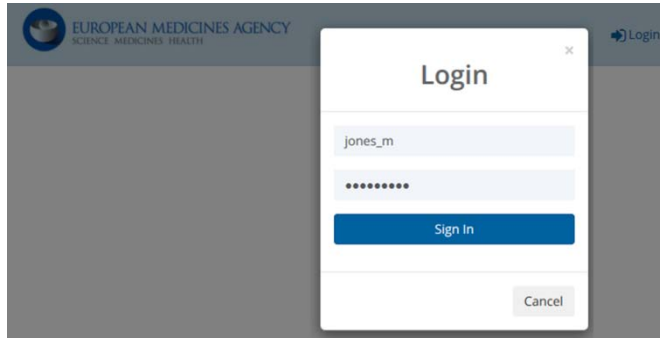
Access
management

Organisation
management



→ Access EV applications

→ XEVMPD



*Log in with EMA unique
credentials*

*select the organisation on behalf
which actions need to be performed*

*Good
to go*

User
management

Access
management

**Organisation
management**

- **Create a new organisation or update an existing one**

Users may create a new organisation or update existing (one add location, etc.).

- **Manage the organisation hierarchy in EV**

Users can:

- Refine organisation details for EV purposes as well as attribute affiliation between organisations.
- Create virtual affiliation of organisations.
- Grant users permission to the virtual affiliates.

IAM2 project

The change introduced



EUROPEAN MEDICINES AGENCY



Responsible

User
management

Access
management

Organisation
management



→ Create a new organisation or update an existing one
→ <https://spor.ema.europa.eu/omswi/#/>

Note: a this is for new organisations after 26 July 2018, existing ones will be migrated from EV to OMS and synchronised back

0/ Make sure you have the role "SPOR Unaffiliated". If not request it, the approval is automatic and instantaneous

1/ Proceed to Organisation Management Services (OMS) on the SPOR portal and log in

2/ Search for an organisation e.g. By means of ID or name.

2/ a) If it exists, you can select it and request a change or add locations

2/ a) If it doesn't exist, a button will appear that allows to create a new organisation

3/ Fill out the form and adding the requested documents

4/ Make sure you have the role "SPOR (super)user". If not, request it, the approval is done by the registration team



* Requesting a SPOR role first is a precondition to create organisations

Manage My Access

Add Access

My Access

Review 1 EV ICSR Browse

Add 1

Showing 1-2 of 2

Filters ▾

**SPOR Unaffiliated**

Details

Type: Role **Owner:** The Administrator**EV ICSR Browse & Send**

Details

Type: Role **Owner:** The Administrator

Add 1

Showing 1-2 of 2





Substances

Products

Organisations

Referentials

Help

SPOR Home

Organisations

Documents



Organisation Management Services (OMS)

OMS provides a central dictionary of organisation data in multiple languages. This covers:

- organisation names;
- location address details;
- communication details such as email address and telephone number per location.

OMS supports the continuous exchange of data between information systems across the European medicines regulatory network and across the pharmaceutical industry.

OMS provides users with the following organisation data management services:

- view, search, export organisation data and change request data;
- request registration of a new organisation or update existing organisation data;
- access to multi-lingual organisation data.

Data management and data quality processes drive the SPOR data management services to ensure that the highest quality of data is available to support EU regulatory processes.

Access to OMS

Use the menus in the navigation panel above to navigate OMS.

Registered users: Log in using the button at the top of this page.

New users: Users that require more than 'read-only' user access should register to create an EMA account before they log in.

[Create EMA Account](#)

About OMS

For more information about using OMS see "[About OMS](#)". This document provides details on:

- data content;
- licensing;
- copyright;
- data protection.

new
26 July
will be
o OMS
back

role
request it,
by the
team

0/ Make sur
"SPOR Un
it, the a





Responsible



EUROPEAN MEDICINES AGENCY SPOR - Organisations Management System

Login

Substances

Products

Organisations

Referentials

Help

SPOR Home

Organisations

Documents

Home / Search Organisations

▼ Hide search

Organisation ID

Contains



Organisation name

Contains



Location ID

Contains



Address

Contains



City

Contains



Postcode

Contains



Country

0 Selected ▼

Modified Since



Location status *

ACTIVE, INACTIVE ▼

Reset

Search



EUROPEAN MEDICINES AGENCY

ation
ment

this is for new
ons after 26 July
ting ones will be
from EV to OMS
chronised back

you have the role
(user". If not request it,
approval is done by the
registration team



0/ Make sup
"SPOR Unap
it, the a

IAM2 project

The change introduced



EUROPEAN MEDICINES AGENCY

Home / Search Organisations / View Organisation Location

Organisation Details

Organisation ID:	ORG-100001482
Organisation Name:	Flynn CL Pharma Ltd
Status:	ACTIVE
Organisation Type:	Industry

Location Details

Location ID:	LOC-100000038
Address:	21 Churchill Place Canary Wharf London E14 5EU United Kingdom
Last Modified Date:	2017-03-12T15:16:57
Last Modified By:	admin
Status:	ACTIVE

Add Location

Request Change

Export

Export With History

* Requesting a SPOR role first is a precondition to create organisations



Substances

Products

Organisations

Referentials

Help

SPOR Home

Organisations

Documents

Organisation
Management

Home / Search Organisations

▼ Hide search

Organisation ID

Contains



Organisation name

Contains



Location ID

Contains



Address

Contains



City

Contains



Postcode

Contains



Country

Modified Since



Location status

Reset

Search

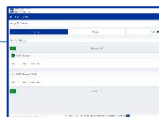
Request New Organisation

precondition to create organisations

this is for new
ations after 26 July
isting ones will be
d from EV to OMS
ynchronised back

are you have the role
per)user". If not request it,
approval is done by the
registration team

0/ Make sure v
"SPOR Unaffili
it, the appr



Substances

Products

Organisations

Referentials

Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations / New Organisation Request

CR Information

CR Type	New Organisation ▼
Request Reason*	▼
Justification	✍
Requestor	Arnaud Berghmans
Contact email*	arnaud.berghmans@gmail.com ⓘ
Contact Phone	

Organisation Details

Organisation Name*	e.g. European Medicines Agency
Acronym	
Organisation Type*	▼

Location Details

Address*	e.g. 30 Churchill Place		
	e.g. Canary Wharf		
City	e.g. London		
Postcode	e.g. E14 5EU		
County	e.g. London		
Country*	▼		
Location Email ⁽¹⁾	e.g. john.doe@ema.europa.eu		
Location Phone ⁽¹⁾	Intl Code: e.g. +44 e.g. 02036606000 Ext:		
DUNS ID	e.g. 01-234-5678		
GSI ID	e.g. 0-00-12345-67890-5		

ⓘ ⁽¹⁾ Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OMS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The Location Email and Location Telephone number are optional fields.

If you have any question about the way your data are being processed please contact EMA at mdms@ema.europa.eu.

Attachments

No documents found, click to add +

Audit trail

Date ▲	Status to ▲ ▼	Comment ▲ ▼
No data available in table		

Cancel

Submit

* Requesting a SPOR role first is a precondition to create organisations

Manage My Access

Add Access

My Access

Review **1** EV ICSR Browse

Add 1

Showing 1-2 of 2

Filters ▾

**SPOR (Super) User**

Details

Type: Role Owner: The Administrator



EV ICSR Browse & Send

Details

Type: Role Owner: The Administrator

Add 1

Showing 1-2 of 2



IAM2 project

The change introduced



EUROPEAN MEDICINES AGENCY



Responsible

User
management

Access
management

Organisation
management



→ Manage the organisation hierarchy in EV
→ EVWEB Registration Application

View the organisation detail
and manage EV specific

Manage the affiliation of
organisations *

Create virtual affiliation of organisations
and grant users permission to the virtual
affiliates

* A responsible needs to have a responsible role for both
organisations to see them

Logged In

adrianmolina
(ORG-david70115 - IT4U - IT4U)
Human Development

EV Services

- ▶ EVWEB - ICSR
- ▶ EVWEB - Art 57 / XEVMPD
- ▶ xEVMPD Export
- ▶ xEVMPD Bulk update
- ▶ EV Data Warehouse
- ▶ EV Post - ICSR
- ▶ EV Post - Art 57 / XEVMPD

EV Registered Partners

- ▶ Manage your profile
- ▶ QPPV List
- ▶ Organisations List

Medical Literature Monitoring

- ▶ MLM Search result
- ▶ MLM ICSRs
- ▶ Archive
- ▶ ICSR Export
- ▶ Substances
- ▶ Further MLM info

User Support

- ▶ EMA Service Desk
- ▶ EVWEB Troubleshooting
- ▶ XEVMPD product export tool user manual
- ▶ XEVMPD Data-Entry Tool (EVWEB) User Manual - product

Organisation being modified: ORG-david70115 - IT4U - IT4U

Organisation EudraVigilance Information

> Organisation Information

Organisation Identifier IT4U
Organisation Name IT4U
Organisation Category Marketing Authorisation Holder
Transmission mode WebTrader
Type of MedDRA licence Low Revenue MedDRA EudraVigilance Fee Waiver
MedDRA Number 1111
Safety reports visibility No
Organisation functional email it4u@it4u.com

> Responsible Information

Street MyStreet123
City Praga
Postal Code 0797565
Area / State
Country Albania

Affiliates

Affiliate ID	Affiliate Name
IT42U	IT42U ldt.
IT43U	IT43U ldt.
IT5U	IT5U-Aff ldt.
IT6U	IT6U-Aff ldt.
IT7U	IT7U-Aff-I have long name very long name how you will display me in the form?

Virtual Affiliates

ID	Name
VA000000027	VA000000027-test-update
VA000000028	VA000000028-test-create
VA000000030	VA000000030, ldt.
VA000000031	VA000000031, ldt.
VA000000032	VA000000032, ldt.
VA000000033	VA000000033
VA000000034	VA000000034, ldt.
VA000000035	VA000000035, ldt

Headquarter Users

Name	Family Name	UserName
Luca	Bolognesi	lucabolognesi
Adrian Molina	Calvo	adrianmolina
Bill	Gates	billgates
David	Mikolanda	davidmikolanda

Printable Version

Update

Manage hierarchy

Create Virtual affiliate



Logged In

adrianmolina
(ORG-david70115 -
IT4U - IT4U)
Human Development

EV Services

- EVWEB - ICSR
- EVWEB - Art 57 / XEVMPD
- xEVMPD Export
- xEVMPD Bulkupdate
- EV Data Warehouse
- EV Post - ICSR
- EV Post - Art 57 / XEVMPD

EV Registered Partners

- Manage your profile
- QPPV List
- Organisations List

Medical Literature Monitoring

- MLM Search result
- MLM ICSRs
- Archive
- ICSR Export
- Substances
- Further MLM info

User Support

- EMA Service Desk
- EVWEB Troubleshooting

Notes:

- To affiliate organisations to the one login on behalf of
- The 'Available Organisations' list displays all organisations the current user is responsible for and which are not already affiliated.
- The 'Current Affiliates' list displays organisations already affiliated to the selected one.
- An SD ticket should be created to de-affiliate an organisation.

Available Organisations

EV Org ID	EV Name
IT41U	IT41U ldt.

Current Affiliates

EV Org ID	EV Name
IT42U	IT42U ldt.
IT43U	IT43U ldt.
IT5U	IT5U-Aff ldt.
IT6U	IT6U-Aff ldt.
IT7U	IT7U-Aff-1 have long name very long name how yo u will display me in the form?

Note: a QPPV, Responsible or Deputy needs to have this role for both an HQ and an affiliate to be able to manage affiliations

>>

Update

Cancel



IAM2 project

The change introduced

EudraVigilance
Human Restricted




EUROPEAN MEDICINES AGENCY

Home Restricted

Home Public

Restricted Area

Logged In

adrianmolina
(ORG- david20115 -
IT4U - IT4U)
Human Development

EV Services

- ▶ EVWEB - ICSR
- ▶ EVWEB - Art 57 / XEVMPD
- ▶ xEVMPD Export
- ▶ xEVMPD Bulk update
- ▶ EV Data Warehouse
- ▶ EV Post - ICSR
- ▶ EV Post - Art 57 / XEVMPD

EV Registered

Partners

- ▶ Manage your profile
- ▶ QPPV List
- ▶ Organisations List

Medical Literature

Monitoring

- ▶ MLM Search result
- ▶ MLM ICSRs
- ▶ Archive
- ▶ ICSR Export
- ▶ Substances
- ▶ Further MLM info

User Support

- ▶ EMA Service Desk
- ▶ EVWEB Troubleshooting
- ▶ xEVMPD product export

Note:

In this screen, responsible users can create Virtual affiliates, assign users to this Virtual affiliate and grant roles to the affiliate users. The responsible of the Headquarter is automatically the responsible of the created Virtual affiliate.
The "Contributor users" list displays all users who have been granted the Contributor role in the EMA Account management platform for the Headquarter.
The "Virtual affiliate user" list displays the users assigned to the virtual affiliate. Selected users can be given ICSR or MPR roles.

For finalising the transmission mode configuration, please open a ticket with the [EMA - Service Desk](#).

Virtual affiliate EudraVigilance Information

Virtual affiliate Identifier	VA000000036
Virtual affiliate Name	
Virtual affiliate Responsible	Luca Bolognesi
Transmission mode	WebTrader
Type of MedDRA licence	Full MedDRA Subscriber
MedDRA Number	

"Contributor" users

Name	Family Name	UserName
Adrian Molina	Calvo	adrianmolina
Bill	Gates	billgates
David	Mikolanda	davidmikolanda

Note: in order for a user to be assigned to a virtual affiliate, this person needs to have requested the role "EV contributor" for the HQ.

After selection of the user in this screen, he will be given a proper role for the given affiliate by selecting the specific role here at the right

Virtual affiliate users

Name	Family Name	UserName	Role
ICSR Roles: ☒ None ☐ EV ICSR Browse ☐ EV ICSR Browse and Send MPR Roles: ☒ None ☐ EV MPR Browse ☐ EV MPR Browse and Send Add Role >> << Remove Role			

Printable Version

Save

Cancel

Disable

organisations to see them





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Marketing authorisation
Post-authorisation

Home > Human regulatory > Post-authorisation > Pharmacovigilance > EudraVigilance > Registration

EudraVigilance: how to register

Email Print Help Share

Pharmaceutical companies holding or applying for a marketing authorisation in the European Economic Area (EEA), sponsors of clinical trials and national competent authorities in the EEA need to register with EudraVigilance for the electronic data interchange of pharmacovigilance information. The registration process is a prerequisite for electronic reporting.

Login for registered users

EudraVigilance XCOMP (Test)

- Details on how to register with EudraVigilance can be found on the Agency's **EudraVigilance registration page**
- Please note that the registration process on this webpage will/has recently been updated to mark the harmonisation to the unique EMA account as of 26 July 2018.
- The upcoming/recent changes are summarised on the next slides

- Users will be able to access the different parts of the EudraVigilance system depending on the access rights assigned to them
- At the time of registration of an organisation a user(s) within that organisation will be assigned the role of administrator which will enable them to:
 - Grant access to new users
 - Remove existing users
 - Set access permissions for users



- The roles and access rights are not changed. Nor are the current assignments in EV. → Just the process and application to request and grant them is made more user friendly and controllable.
- The user still requests an EV role for a given organisation and the QPPV/responsible for that given organisation grants or rejects the requested access. → It will become self manageable.
- The QPPV or designated deputy acts as central point in the organisation for the registration proces. The QPPV/responsible can still delegate his tasks to multiple other designated deputies. → It will become self manageable.
- The validation and certification of the first QPPV/responsible of an organisation by the EMA Service Desk, both for request access and request removal access.
- The possibility to de-assign a user from its role. → It will become self manageable.
- The way hierarchy of organisation is managed in EV, including the concept of virtual affiliates inside EV.
- The process to perform business mergers, swaps, splits, etc. The EMA Service Desk still needs to be requested to perform based on valid business documentation.